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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,542

03/29/2004

Gerald D. Buckberg

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12/07/2006

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EXAMINER

ISABELLA, DAVID J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/811,542	Applicant(s) BUCKBERG ET AL.	
	Examiner DAVID J. ISABELLA	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-11, 14, 15, 21, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-11, 14, 15, 21, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

The preliminary amendment filed July 12, 2006 has been entered.

Claims 12,13,16-20 and 22 have been cancelled. Claims 7,14,21 have been amended. Currently claims 7-11,14,15,21,23 and 24 are pending for action.

***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-11, 14,15,21,23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dor ("*Left Ventricular Aneurysms: The Endoventricular Circular Patch Plasty*", as cited in applicant's IDS) in view of Mulhauser, et al [5766246] and Das [5334217].

Dor discloses method for restoring the ventricular architecture of a heart having an anterior wall and an inferior wall with all the elements of claims 7 and 16, but is silent to the limitations of a triangular continuous ring being fixed to the sheet, as required by

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claims 7 and 16, and sewing the continuous ring to the inner surface of the inferior wall along the suture line to restore the ventricular architecture of the heart, as further required by claim 7. See Figure 1 for creating an incision in the inferior wall of the heart to expose an inner surface of the ventricle. See Figure 2 for forming a suture line around the inner surface of the inferior wall. See Figure 5 for providing a ventricular patch having a sheet of biocompatible material. Mulhauser et al and Das teach a cardiac reinforcement patch in Figures 5a-5f (of Das) and column 4 (of Mulhauser et al) for locally constraining cardiac expansion including a continuous outer frame/sewing fixed to the sheet of biocompatible material in order to reinforce the patch for attachment by sutures of the patch to the heart, thereby restoring the ventricular architecture of the heart. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Das and/or Mulhauser, et al to modify the triangular patch of Dor by including a continuous frame/sewing ring in order to reinforce the patch for attachment by sutures of the patch to the heart. Because the ring is attached to the peripheral edge (4) of the patch, the shape of the ring will reflect the shape of the patch. Therefore, including a ring to the peripheral edge of the patch of Dor will mean that the ring is triangular in shape. Also, because the periphery of the patch of Dor is sewn to the inner surface of the inferior wall along the suture line to restore the ventricular architecture of the heart, the inclusion of the peripheral ring will mean that the ring will be sewn to inner surface of the inferior wall along the suture line. Mulhauser et al teaches providing an outer rim of the patch that extends outwardly of the ring for sewing the patch to the affected tissue. The use of

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peripheral outer rim of material/patch beyond the reinforcing ring for attaching the patch to the tissue would have been obvious to one with ordinary skill in the art from the teachings of Mulhauser et al.

Claim 8, see abstract and the second paragraph in the second column of page 124 for creating an incision in the non-contracting region of the inferior wall and Figure 1 for opening the incision to expose an inner surface of the heart.

Claim 9, see abstract and the third paragraph in the second column of page 124 and Figure 2 for forming a suture line generally along the line of separation.

Claim 10, see Figure 5 for spreading the incision to create a triangular opening extending into the ventricle of the heart.

Claims 11, 14 and 17, see Mulhauser et al. The outer rim of the patch is interpreted as the portion of the biocompatible material to which the continuous ring is fixed. Because the continuous ring has a constant width, the outer rim of the patch will have a constant width around the central area of the patch.

Claims 15 and 20, see either of Das or Mulhauser et al for the sheet of biocompatible material being in the shape of a triangle.

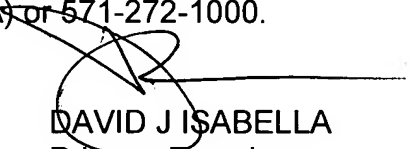
Claim 21, see rejection to claim 7 supra.

Claims 23 and 24, see rejections to corresponding claims supra.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
12/4/2006